WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB134 trade name]*

Ethambutol hydrochloride 400 mg film-coated tablets

[TB134 trade name], manufactured at Macleods Pharmaceuticals Ltd, Daman, India was accepted for the WHO list of prequalified medicinal products for the treatment of tuberculosis on 23 March 2007.

[TB134 trade name] is indicated in combination with other anti-tuberculosis agents for the treatment of multi-drug resistant tuberculosis caused by *Mycobacterium tuberculosis*. Detailed information on the use of this product is described in the Summary of Product Characteristics (SmPC), which can be found in this WHOPAR.

The active pharmaceutical ingredient (API) of [TB134 trade name] is the antimycobacterial agent ethambutol.

The efficacy and safety profile of ethambutol is well established based on extensive clinical experience in the treatment of tuberculosis.

For details on the uses of this product and for side effects and warnings, see Part 4 of this WHOPAR (summary of product characteristics).

On the basis of data submitted and public information on antituberculosis therapy, the team of assessors advised that [TB134 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB134 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [TB134 trade name]:

Initial Acceptance	**Date**	**Outcome**
Status on PQ list	23 March 2007	Listed
Dossier Evaluation		
Quality	25 January 2007	MR
Bioequivalence	1 February 2006	MR
Safety, Efficacy	NA	NA
GMP (re-inspection)		
APIs	30 November 2005	MR
FPP	23 May 2005	MR
GCP (re-)inspection	26 May 2006	MR

API: active pharmaceutical ingredient
FPP: finished pharmaceutical product
GCP: good clinical practice [quality standard]
GLP: good laboratory practice [quality standard]
GMP: good manufacturing practice [quality standard]
MR: meets requirements
MR*: desk review (based on recent inspection reports)
NA: not applicable, not available
PQ: prequalification

The table represents the status of relevant completed activities only.

Requalification

Status on PQ list	20 September 2023.	MR

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility